UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH DEVICES LIABILITY LITIGATION	**Case No. 2:18-md-2846** **CHIEF JUDGE EDMUND A. SARGUS, JR.** **Magistrate Judge Kimberly A. Jolson**

This document relates to:
ALL ACTIONS.

MASTER LONG FORM COMPLAINT

Plaintiffs, by and through the undersigned lead counsel, file this Master Long Form Complaint as an administrative method to set forth potential claims individual Plaintiffs may assert against Defendants in this litigation. By operation of Case Management Order No. 9, all allegations pled in this Master Long Form Complaint are deemed pled in any Short Form Complaint filed in the future.[1]

This Master Long Form Complaint does not necessarily include all claims asserted in all of the transferred actions to this Court, nor is it intended to consolidate, for any purpose, the separate claims of Plaintiffs in this MDL. Any separate facts and additional claims of individual Plaintiffs may be set forth in the Short Form Complaints filed by the respective Plaintiffs or their counsel. This Master Long Form Complaint does not constitute a waiver or dismissal of any actions or claims asserted in any individual action, nor do any Plaintiffs relinquish the right to

[1] The Short Form Complaint, which incorporates the Master Long Form Complaint by reference, is attached as Exhibit A. It is to be used by every Plaintiff who files a case in this Court pursuant to CMO 2 (Direct Filing Order) and CMO 9 (Governing Initial Pleadings).

move to amend their individual claims to seek any additional claims as discovery proceeds and facts and other circumstances may warrant.

Plaintiffs allege the following:

I. PARTIES

PLAINTIFFS

1. Plaintiffs are men and women implanted with one or more of Defendants' Polypropylene Hernia Mesh Devices ("Hernia Mesh Devices," or "Devices") to repair their hernias. The Devices are listed in Paragraph No. 15 of this Master Long Form Complaint.

2. Plaintiffs may also include the spouses of the individuals implanted with the Hernia Mesh Devices, as well as others with standing to assert claims arising from and/or damages resulting from the Devices. Those Plaintiffs will be identified in the Short Form Complaint and are referred to as "Consortium Plaintiffs."

DEFENDANTS

3. Defendant Davol, Inc. ("Davol") is a subsidiary of Defendant C.R. Bard, Inc. ("Bard"). Davol is incorporated in Delaware and has its principal place of business in Rhode Island. Davol is a medical device company involved throughout all states and territories in the United States in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices, including the Hernia Mesh Devices in this litigation. Defendant Davol has derived substantial revenue related to Hernia Mesh Devices from its business throughout each of the states and territories of the United States.

4. Upon information and belief, Davol designed, initially manufactured, and first placed the Hernia Mesh Devices on the market from its headquarters in Rhode Island.

5. Upon information and belief, Davol corporate executives drafted FDA communications pertaining to the Hernia Mesh Devices from its headquarters in Rhode Island.

6. Upon information and belief, Davol also conducts all sales force oversight and training management from its Rhode Island headquarters, and the Davol Biosurgery Surgical Education Program is managed from its Rhode Island headquarters.

7. Defendant Bard is incorporated and based in New Jersey and is the corporate parent/stockholder of Davol. It is a multinational developer, manufacturer, producer, seller, marketer, and promoter of medical devices. Bard controls the largest U.S. market share of hernia mesh devices and participates in the manufacture and distribution of the Hernia Mesh Devices in this litigation throughout all states and territories of the United States. It also manufactures and supplies Davol with material forming part of the Hernia Mesh Devices. Defendant Bard has derived substantial revenue related to Hernia Mesh Devices from its business throughout the states and territories of the United States.

8. Bard was at all material times responsible for the actions of Davol. It exercised control over Davol's functions specific to the oversight and compliance with applicable safety standards regarding Hernia Mesh Devices sold throughout the states and territories of the United States. In such capacity, Bard committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to manufacturing, quality assurance/control, and conformance with design and manufacturing specifications.

9. Davol and Bard (collectively "Defendants") are individually and jointly and severally liable to Plaintiffs for damages they suffered arising from the design, manufacture, marketing, labeling, improper/inadequate warnings, distribution, sale, and placement of Defendants' Hernia Mesh Devices, effectuated directly and indirectly through Defendants' agents,

servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

10. Defendants have expected or should have expected their acts to have consequences within each of the states and territories of the United States, and have derived substantial revenue related to the Hernia Mesh Devices from interstate commerce in each of the states and territories of the United States.

11. Defendants are also vicariously liable for the acts and omissions of their employees and/or agents who were at all material times acting on Defendants' behalf and within the scope of their employment or agency.

II. JURISDICTION AND VENUE

12. Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332(a), in that complete diversity of citizenship between every Plaintiff and Defendants exists in each constituent action, and the amount in controversy exceeds $75,000 in each.

13. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, Defendants are subject to personal jurisdiction in the federal judicial district identified in the Short Form Complaint.

14. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the federal judicial district identified in the Short Form Complaint. Venue is proper in that federal judicial district pursuant to 28 U.S.C. §1391(a).

III. FACTS COMMON TO ALL COUNTS

DAVOL/BARD HERNIA MESH DEVICES

15. Defendants' Hernia Mesh Devices in this litigation are defined as hernia mesh devices that were designed, manufactured, marketed, labeled, distributed, sold, or otherwise placed

on the market by Defendants and are comprised in whole or in part of polypropylene, including the 21 related products listed and described below:

a) **3DMax Light Mesh:** Large pore, lightweight polypropylene, three-dimensional concave mesh.

b) **3DMax Mesh:** Small pore, heavyweight polypropylene, three-dimensional concave mesh.

c) **Bard (Marlex) Mesh Dart:** Three-dimensional, dart-like structure with multiple layers of small pore, heavyweight polypropylene. Dart-like component is stitched to a layer of small pore, heavyweight polypropylene.

d) **Bard Mesh:** Small pore, heavyweight polypropylene.

e) **Composix**: Double layer, small pore, heavyweight polypropylene heat-sealed to a single layer of expanded polytetrafluoroethylene (ePTFE).

f) **Composix E/X**: Double layer, small pore, heavyweight polypropylene stitched to single layer of ePTFE.

g) **Composix Kugel Hernia Patch**: Two layers of small pore, heavyweight polypropylene attached to a single layer of ePTFE. Contains a permanent internal polyethylene terephthalate (PET) ring to help maintain its shape. The PET ring was the subject of an FDA Class I Recall in 2005, 2006, and 2007.

h) **Composix L/P:** Single layer of large pore, lightweight polypropylene attached to a layer of ePTFE.

i) **Kugel Hernia Patch:** Two layers of small pore, heavyweight polypropylene with a permanent oval PET memory ring.

j) **Marlex**: Small pore, heavyweight polypropylene.

k) **Modified Kugel Hernia Patch**: Two layers of small pore, heavyweight polypropylene with a permanent circular PET memory ring. Preshaped onlay patch included.

l) **PerFix Light Plug**: Three-dimensional, dart-like structure with multiple layers of large pore, lightweight polypropylene. A separate flat, large pore lightweight polypropylene onlay is included.

m) **PerFix Plug:** Three-dimensional, dart-like structure with multiple layers of small pore, heavyweight polypropylene. A separate flat, small pore heavyweight polypropylene onlay is included.

n) **Sepramesh IP:** Small pore, heavyweight polypropylene adhered to a resorbable layer composed of modified sodium hyaluronate (HA),

carboxymethylcellulose (CMC) and polyethylene glycol (PEG) based hydrogel via acidic polymers and heat pressing.

o) **Sperma-Tex:** Small pore, heavyweight polypropylene adhered to a layer of ePTFE on one side at the rounded corner.

p) **Ventralex Hernia Patch:** Two layers of small pore, heavyweight polypropylene adhered to a sheet of ePTFE. Through 2013, contained a permanent PET memory recoil ring. After 2013, moved to a resorbable memory ring composed of extruded polydioxanone (PDO) within a knitted polypropylene mesh tube. Includes polypropylene straps to aid in mesh placement and positioning.

q) **Ventralex ST Patch:** Layer of large pore, lightweight polypropylene adhered to a Sepramesh. Resorbable memory ring composed of extruded PDO within a knitted polypropylene mesh tube. Includes polypropylene straps to aid in mesh placement and positioning.

r) **Ventralight ST:** Small pore, lightweight polypropylene adhered to a resorbable HA/CMC layer via acidic polymers and heat pressing.

s) **Ventrio Patch:** Two layers of small pore, heavyweight polypropylene adhered to a sheet of ePTFE. Resorbable memory ring composed of extruded PDO within a knitted polypropylene mesh tube.

t) **Ventrio ST:** Layer of large pore, lightweight polypropylene adhered to a Sepramesh. Resorbable memory ring composed of extruded PDO within a knitted polypropylene mesh tube.

u) **Visilex:** Small pore, heavyweight polypropylene, honeycomb design.

16. Defendants sought and obtained FDA clearance to market their Hernia Mesh Devices under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. The 510(k) process is not a formal review for safety or efficacy. No clinical testing or clinical study is required to gain FDA clearance under this process. Upon information and belief, no formal review for safety or efficacy was ever conducted for the Hernia Mesh Devices.

POLYPROPYLENE IN HERNIA MESH DEVICES: DEFECTS & RISKS

17. Defendants' Hernia Mesh Devices share one common denominator: they all contain polypropylene. Despite Defendants' claims that polypropylene is inert, scientific evidence shows it is biologically incompatible with human tissue, and promotes an immune response in much of the population receiving it. The immune response to polypropylene promotes degradation and contracture of the mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the Hernia Mesh Devices.

18. The numerous suppliers to Defendants of various forms of polypropylene cautioned all users in their U.S. Material Safety Data Sheets (MSDS) that polypropylene was not to be used for medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

19. The Hernia Mesh Devices are defective due to their high rates of failure, injury, and complications, their failure to perform as intended, their requirement of frequent and often debilitating re-operations, and their cause of severe and irreversible injuries, conditions, and damage to numerous patients, including Plaintiffs.

20. The specific nature of the Hernia Mesh Devices' defects includes, but is not limited to, the following:

a) The use of polypropylene in the Devices and the immune reactions resulting from such material, cause adverse reactions and injuries.

b) Adverse reactions to the polypropylene in the Devices consist of adhesions, injuries to nearby organs, nerves, or blood vessels, and other complications, including infection, chronic pain, and hernia recurrence.

c) The Devices have a propensity to degrade or fragment over time, causing a chronic inflammatory and fibrotic reaction, and resulting in continuing injury over time as the polypropylene acts as a chronic trigger for inflammation.

d) Upon information and belief, Defendants utilized various substandard and/or adulterated polypropylene resins in the Devices.

e) The weave of the polypropylene mesh produces very small interstices allowing bacteria to enter and hide from white blood cells and macrophages—the host defenses designed to eliminate bacteria. The bacteria also secrete an encasing biofilm, serving to further protect them from destruction by white blood cells and macrophages. In addition, some bacteria are capable of degrading polypropylene.

f) Polypropylene is always impure; there is no pure polypropylene. Polypropylene contains about 15 additional compounds that leach from the product and are toxic to tissue, enhancing the inflammatory reaction and the intensity of fibrosis.

g) Scanning electron microscopy has shown mesh to not be inert, with degradation leading to flaking, fissuring, and release of toxic compounds. This enhances the inflammatory and fibrotic reactions.

h) By 1998 at the latest, polypropylene mesh was known to shrink 30-50%.

i) Polypropylene is subject to oxidation by acids produced during the inflammatory reaction, causing degradation and loss of compliance.

j) Mesh porosity is important for tissue ingrowth, with low porosity decreasing tissue incorporation. Porosity also affects the inflammatory and fibrotic reaction. With mechanical stress, the effective porosity is decreased.

k) After implantation in the human body, polypropylene is known to depolymerize, cross-link, undergo oxidative degradation by free radicals, and stress crack.

l) The large surface area of polypropylene promotes wicking of fluids and bacteria, and is a "bacterial super highway" providing a safe haven for bacteria.

m) Common complications associated with polypropylene include restriction of abdominal wall mobility and local wound disturbances. Failures of polypropylene often include persistent and active inflammatory processes, irregular or low formation of scar tissue and unsatisfying integration of the mesh in the regenerative tissue area.

21. Shrinkage and stiffness of flexible meshes is affected by scar tissue. The majority of the Hernia Mesh Devices have smaller inter-filament distances and pores that increase the risk of bridging by scar tissue.

22. In most Devices, Defendants use heavyweight, small pore polypropylene, which increases inflammation, foreign body response, and subsequent complications.

23. Although Hernia Mesh Devices mostly utilize the heavyweight, small pore polypropylene, Defendants implemented a design modification in some Devices—lighter weight polypropylene with larger pores. But Defendants knew or should have known that the benefit of larger pores becomes irrelevant in folded or multilayered mesh (*e.g.*, Composix L/P and Ventralight ST), and in the designs that allow significant pore collapse (*e.g.*, Perfix Light Plug and 3D Max Light Mesh).

24. Defendants knew or should have known that the Hernia Mesh Devices implanted in the groin will be subject to movement and bending. Polypropylene in the groin has a higher likelihood of folding and bunching, and the scar fills the spaces between the folds. The phenomenon was termed a "meshoma" because the mesh forms a tumor-like mass. Therefore, the implementation of the lightweight polypropylene in inguinal (groin) devices (*e.g.*, PerFix Light Plug and 3D Max Light Mesh) did not cure any defects inherent in the Hernia Mesh Devices as described in this Master Complaint. Further, in 2018 the HerniaSurge Group published *International Guidelines for Groin Hernia Management,* which advised: "The incidence of erosion seems higher with plug versus flat mesh. It is suggested not to use plug repair techniques." These guidelines have been endorsed worldwide by hernia mesh societies.

DEFENDANTS' ACTS & OMISSIONS REGARDING THEIR DEFECTIVE DEVICES

25. At all material times, Defendants Bard and Davol were responsible for designing, manufacturing, producing, testing, studying, inspecting, labeling, marketing, advertising, selling, promoting, and distributing their Hernia Mesh Devices, and providing warnings/information about the Devices.

26. Defendants' Devices were defectively designed and manufactured; and were also defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing, despite Defendants' knowledge of the Devices' lack of safety.

27. Defendants had independent obligations to know and timely and adequately disclose scientific and medical information about their Hernia Mesh Devices; and to warn of their risks and side effects as soon as each Defendant was aware of them. Neither Defendant did so.

28. Defendants also knew or should have known that their Hernia Mesh Devices unreasonably exposed Plaintiffs to the risk of serious harm, while conferring no benefit over available feasible and safer alternatives that did not present the same risks and adverse effects.

29. Defendants made claims regarding the benefits of implanting the Devices but minimized or omitted their risks and adverse effects. Although Defendants knew or should have known that their claims were false and misleading, they failed to adequately disclose the true health consequences and the true risks and adverse effects of the Hernia Mesh Devices.

30. At all material times, Defendants Bard and Davol failed to provide sufficient warnings and instructions that would have put Plaintiffs, their health care providers, and the general public on notice of the dangers and adverse effects caused by implantation of the Hernia Mesh Devices.

31. Defendants have marketed and continue to market their Hernia Mesh Devices to Plaintiffs and health care providers as safe, effective and reliable, and implantable by safe and effective, minimally invasive surgical techniques. Further, Defendants continue to market their Devices as safer and more effective than available feasible alternative treatments for hernias, and other competing products. Those alternatives have existed at all material times, and have always presented less frequent and less severe risks and adverse effects than the Hernia Mesh Devices.

32. The risks of the Hernia Mesh Devices' design outweigh any potential benefits associated with the design. As a result of their defective design and/or manufacture, an unreasonable risk of severe adverse reactions can occur, including but not limited to: foreign body response; granulomatous response; allergic reaction; rejection; erosion; excessive and chronic inflammation; adhesions to internal organs; scarification; improper wound healing; infection; seroma; abscess; fistula; tissue damage and/or death; nerve damage; chronic pain; recurrence of hernia; and other complications.

33. Defendants omitted mention of the Devices' risks, dangers, defects, and disadvantages when they advertised, promoted, marketed, sold and distributed them as safe to regulatory agencies, health care providers, Plaintiffs and other consumers. But Defendants knew or should have known that the Hernia Mesh Devices were not safe for their intended purposes, and that they would and did cause serious medical problems, including severe and permanent injuries and damages—and in some Plaintiffs, catastrophic injuries and death.

34. Defendants have underreported information about the propensity of the Hernia Mesh Devices to fail and cause injury and complications; and have made unfounded representations regarding the efficacy and safety of the Devices through various means and media.

35. Defendants knew or should have known that at all material times their communications about the benefits, risks and adverse effects of the Hernia Mesh Devices, including communications in labels, advertisements and promotional materials, were materially false and misleading.

36. Defendants' nondisclosures, misleading disclosures, and misrepresentations were material and were substantial factors contributing directly to the serious injuries and damages Plaintiffs have suffered.

37. Plaintiffs would not have agreed to allow the implantation of the Hernia Mesh Devices had Defendants disclosed the true health consequences, risks and adverse effects caused by their Hernia Mesh Devices.

38. Upon information and belief, Defendants Bard and Davol failed to conduct adequate pre-market clinical testing and research, and failed to conduct adequate post-marketing surveillance to determine the safety of the Hernia Mesh Devices.

39. Upon information and belief, Defendants failed to disclose on their warning labels or elsewhere that adequate pre-market clinical testing and research, and adequate post-marketing surveillance had not been done on the Hernia Mesh Devices, thereby giving the false impression that the Devices had been sufficiently tested.

40. The Hernia Mesh Devices are defective due to Defendants' failure to adequately warn or instruct Plaintiffs and their health care providers concerning at least the following subjects:

a) The Hernia Mesh Devices' propensities for degradation and fragmentation.

b) The rate and manner of mesh erosion or extrusion in the Devices.

c) The risk of chronic inflammation resulting from the Devices.

d) The risk of chronic infections resulting from the Devices.

e) The Devices would be "tension free" only at the time of implantation; and would drastically contract once implanted.

f) The risk of recurrent hernias, intractable hernia pain, and other pain resulting from the Devices.

g) The need for corrective or revision surgery to revise or remove the Devices.

h) The severity of complications that could arise as a result of implantation of the Devices.

i) The hazards associated with the Devices.

j) The Devices' defects described in this Master Complaint.

k) Treatment of hernias with the Devices is no more effective than with feasible available alternatives; and exposes patients to greater risk than with feasible available alternatives.

l) Treatment of hernias with the Devices makes future surgical repairs more difficult than with feasible available alternatives.

m) Use of the Devices puts patients at greater risk of requiring additional surgery than use of feasible available alternatives.

n) Complete removal of the Devices may not be possible and may not result in complete resolution of the complications, including pain.

o) The Hernia Mesh Devices are cytotoxic, immunogenic, and/or non-biocompatible, causing or contributing to complications such as delayed wound healing, chronic inflammation, adhesion formation, foreign body response, rejection, infection, seroma formation, and others.

p) The Devices significantly contract and harden post-implantation.

41. The Hernia Mesh Devices were at all times utilized and implanted in a manner foreseeable to Defendants: Defendants generated Instructions for Use for the Devices, created implantation procedures, and allegedly trained the implanting physicians. But Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Devices, subsequent anatomical changes, and aftercare of patients, including Plaintiffs.

42. The Hernia Mesh Devices implanted in Plaintiffs were in the same or substantially similar condition as when they left Defendants' possession, and in the condition directed by and expected by Defendants.

43. As a result of having the Hernia Mesh Devices implanted, Plaintiffs have experienced significant physical and mental pain and suffering, sustained permanent injury, undergone medical treatment and will likely undergo further medical treatment, and suffered financial or economic loss, including obligations for medical services and expenses, lost income, and other damages.

ADDITIONAL DEFECTS: CERTAIN HERNIA MESH DEVICES

44. At all material times, Defendants had a financial incentive to increase both the number of surgeons implanting their Devices, and the rate of their implantation. Hernia Mesh Devices that could be implanted inside the peritoneal cavity (intraperitoneally) would further this purpose because Defendants could tout the ease and speed of implantation.

45. Extreme risks of adhesion formation, bowel complications, erosion, fistula formation, and other complications occur when a polypropylene device is placed intraperitoneally, *i.e.*, next to the bowel and other organs. So Defendants instituted design modifications intended to separate the dangerous polypropylene base material from patients' internal organs when their Hernia Mesh Devices are placed intraperitoneally.

46. As described more fully below, some of the Hernia Mesh Devices utilize a biodegradable hydrogel layer known as Sepra® Technology, which, with the exception of Sepramesh IP, are denoted by the presence of "ST" within the product name ("ST Devices"). Another subset of Defendants' Devices utilizes a layer of non-porous plastic known as "expanded polytetrafluoroethylene" or ePTFE ("ePTFE Devices"). But in both the ST Devices and ePTFE Devices, the additional layers applied to the already-defective and dangerous polypropylene Hernia Mesh Devices merely create added defects and risks.

"ST DEVICES": ADDED DEFECTS & RISKS

47. Defendants' ST Devices were defectively designed and/or manufactured, and were not reasonably safe for their intended use in hernia repair. Further, the risks of the design outweighed any potential benefits associated with the design.

48. As a result of the defective design and/or manufacture of the ST Devices, an unreasonable risk of severe adverse reactions can occur, including but not limited to: foreign body

response; granulomatous response; allergic reaction; rejection; erosion; excessive and chronic inflammation; adhesions to internal organs; scarification; improper wound healing; infection; seroma; abscess; fistula; tissue damage and/or death; tumor formation, cancer, nerve damage; chronic pain; recurrence of hernia; and other complications.

49. When ST Devices are implanted in the body, their impermeable coating prevents fluid escape, leading to seroma formation, which in turn can cause infection or abscess formation and other complications. The coating of the ST Devices, intended to prevent adhesion formation to the polypropylene portion of the mesh, resorbs within 7 days. But the period in which adhesions can form exceeds 7 days.

50. Acidic polymers are used to bond the coating to the polypropylene of the ST Devices. The acidic polymers cause at least the following:

- inhibit the body's natural defenses by lowering the pH of the intraperitoneal cavity;
- result in delayed wound healing, adhesion formation, infection, foreign body response, rejection, and other complications, because they are highly inflammatory and take several months to resorb; and
- further exacerbate the degradation of polypropylene.

51. The ST coating of the ST Devices, which was marketed, promoted and intended as an adhesion barrier, was only temporary—it was expected and intended to degrade over time inside the body. Thus, the coating potentially prevented tissue ingrowth for only the first few days. As it degraded within a week, the coating left the "naked" polypropylene mesh and acidic polymers exposed to the viscera. Once exposed, the inflammatory nature of the polypropylene and the acidic polymers inevitably stimulated adhesion formation and eventually adhered to the viscera, initiating a cascade of adverse consequences.

52. The polypropylene mesh within the defective coating of the ST Devices was in itself dangerous and defective, especially when utilized in the manner intended by Defendants.

Further, the particular polypropylene material in the ST Device was substandard, adulterated and/or non-medical grade, and was unreasonably subject to oxidative degradation within the body, additionally exacerbating the adverse reactions to the product once the ST coating degraded. When implanted adjacent to the bowel and other internal organs, as Defendants intended for the ST Devices, the organs are unreasonably susceptible to adhesion formation, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, as well as other injuries.

53. Defendants knew or reasonably should have known that any purported beneficial purpose of the coating (*i.e.*, to prevent adhesions to the bowel and other viscera) did not exist. The coating provided no benefit, while substantially increasing the risks to Plaintiffs and others.

54. Some ST Devices include a resorbable inner ring of polydioxanone (PDO), to aid in the short-term memory and stability of the device. The inner PDO ring is called "SorbaFlex Memory Technology." Once implanted, the PDO ring breaks down via hydrolysis over a period of at least 6 to 8 months. The PDO ring elicits an intense inflammatory response during absorption.

DEFENDANTS' ACTS & OMISSIONS REGARDING "ST DEVICES"

55. Defendants provided no warning about the risks/increased risks specifically associated with the unique design of the ST Devices, including the fact that the ST coating of the ST Devices could resorb within a few days.

56. No other polypropylene surgical mesh sold in the U.S. has the dangerous and defective ST coating with acidic polymers, which themselves cause or increase the risks of numerous complications, including but not limited to: seroma; infection; immunologic response; inflammatory reaction; foreign body response; and adhesions.

57. Defendants' Instructions for Use for the ST Devices also failed to adequately warn Plaintiffs' health care providers of numerous risks that Defendants knew or should have known

were associated with the ST Devices. They include but are not limited to: immunologic response; pain; dehiscence; encapsulation; rejection; migration; scarification; contraction; increased adhesions to internal organs and viscera; bowel obstruction; erosion through adjacent tissue and viscera; infection; and hernia incarceration or strangulation.

58. Defendants expressly intended for their ST Devices to be implanted in contact with the bowel and internal organs; and marketed and promoted them for that purpose. Although Defendants represented to health care providers that the ST coating would prevent or reduce adhesions, they failed to warn them that adhesions would still form long after the ST coating resorbs, and therefore at best would provide only a temporary adhesion barrier. Further, Defendants did not warn health care providers that when the coating inevitably degraded, the exposed polypropylene and acidic polymers would become adhered to the bowel or tissue.

59. With respect to Defendants' warnings about the complications associated with the ST Devices, they provided no information about their frequency, severity and duration—even though the complications were more frequent, more severe and longer lasting than those associated with existing safer feasible alternative hernia repair treatments.

60. If Plaintiffs or their health care providers had been properly warned of the defects and dangers of Defendants' ST Devices, and of the frequency, severity and duration of the risks associated with the ST Devices, Plaintiffs would not have consented to allow them to be implanted, and their health care providers would not have implanted the Devices in Plaintiffs.

"ePTFE DEVICES": ADDED DEFECTS & RISKS

61. Defendants' ePTFE Devices were defectively designed and/or manufactured, and were not reasonably safe for their intended use in hernia repair. Further, the risks of the design outweighed any potential benefits associated with the design.

62. As a result of the defective design and/or manufacture of the ePTFE Devices, an unreasonable risk of severe adverse reactions can occur, including but not limited to: seroma; infection; sepsis; abscess; fistula; adhesions; organ perforation; recurrence of hernia; foreign body response; excessive and chronic inflammation; erosion; rejection; improper wound healing; allergic reaction; granulomatous response; nerve damage; chronic pain; tumor formation, cancer, tissue damage and/or death; and other complications.

63. When implanted in the body, the ePTFE layer of the ePTFE Devices prevents normal fluid transportation within the body. This causes various fluids to pool, leading to seroma formation, which in turn can increase the risk of infection, sinus tract or abscess formation, and other complications.

64. ePTFE provides an ideal bacteria breeding ground, in which bacteria cannot be eliminated by the body's immune response, thus allowing infection to proliferate.

65. The solid, flat, relatively smooth and continuous surface of Defendants' ePTFE Devices inhibits the body's ability to clear toxins.

66. The ePTFE Devices are defective in their design in part because of a material mismatch—ePTFE shrinks at a significantly faster rate than polypropylene. This material mismatch results in an ePTFE Device contracting and/or deforming after implantation, exposing the polypropylene side to viscera. Thus, as the mesh deforms and further deviates from a flat design, the foreign body response and complications increase.

67. ePTFE contracts due to the body's inflammatory and foreign body response. But polypropylene incites a greater inflammatory and foreign body response than ePTFE alone. Defendants' ePTFE/polypropylene combination design results in the ePTFE layer shrinking faster than ePTFE would if not in the presence of polypropylene.

68. Bacterial adherence is increased due to the interstitial porosity, surface tension, and electronegativity of ePTFE.

69. ePTFE undergoes irreversible structural changes in the presence of infection or microorganisms. Those changes create small nooks and crannies, which are large enough to harbor microorganisms but too small for various white blood cells and other infection fighters to enter. Additionally, as ePTFE changes structurally due to degradation, the surface becomes rougher and can kill responding white blood cells. ePTFE degradation-related structural changes protect microorganisms, allowing them to flourish, necessitating total removal of the ePTFE Devices.

70. As ePTFE degrades, small fragments can break off and migrate through the body. And they can harbor bacteria, providing a long-term source for future implants to become infected.

71. Some ePTFE Devices include a resorbable inner ring of PDO, to aid in the short-term memory and stability of the device. Once implanted, the PDO ring breaks down via hydrolysis over a period of at least 6 to 8 months. The PDO ring elicits an intense inflammatory response during absorption.

DEFENDANTS' ACTS & OMISSIONS REGARDING "ePTFE DEVICES"

72. Defendants failed to warn and instruct Plaintiffs and their health care providers concerning the defects and risks in ePTFE Devices. The following warnings were never given:

a) The ePTFE Device needed to be much larger than the hernia defect for an effective repair (omitted from Instructions for Use).

b) The ePTFE Device would shrink; and the extent to which it would shrink (omitted from Instructions for Use).

c) The ePTFE Device would be "tension free" only at the time of implantation; and would drastically contract once implanted.

d) The ePTFE Device would degrade in the presence of bacteria, harbor bacteria, and prevent an infection from clearing.

e) Surgical intervention is needed in the event of complications; and the proper treatment of such complications.

f) Surgical removal of the ePTFE Device in the event of complications would leave the hernia unrepaired; leave a much larger hernia than the original; and would necessitate more complicated treatment to attempt to repair the hernia.

g) In the event of complications, the ePTFE Device is more difficult to fully remove than other feasible and available hernia mesh devices.

h) ePTFE Device implantations will leave Plaintiffs at a higher risk of infection for the remainder of their lives.

PET-RINGED DEVICES: ADDED DEFECTS & RISKS

73. Some of Defendants' Devices contain one or more defectively designed polyethylene terephthalate (PET) rings.

74. Defendants' PET-ringed ePTFE Devices, such as the Composix Kugel Hernia Patch and some models of the Ventralex Hernia Patch, were the only hernia mesh devices on the market that contained a PET ring.

75. These PET-ringed Devices are vulnerable to buckling, folding, breaking, and/or migrating due to weaknesses in the PET ring, and the strain put on the PET ring as the polypropylene and/or ePTFE shrink post-implantation.

76. The risks of Defendants' PET-ringed Devices significantly outweigh any benefits Defendants contend could be associated with them. The only stated purpose of the ring is to facilitate initial placement of the device by the surgeon, yet by design it is left implanted along with the other components of the Device. However, the implanted PET ring exposes patients to a lifetime of risk of serious injury or death from bowel perforation, fistula, or other injuries.

77. As noted above, these PET-ringed Devices are exposed to contraction forces once implanted in the human body. Resisting this contraction force, the PET ring struggles to maintain its shape. As the device loses more surface area due to scar contracture or degradation, the forces

acting on the PET ring increase as a result. Additionally, patient movement, such as bending, adds additional force on the PET ring that can result in breaking or buckling of the Device. The PET ring can also suffer degradation. Because of these factors, the PET ring can permanently buckle, kink, bend, or break.

78. If the PET ring buckles in a PET-ringed ePTFE Device, it may flip over or bow, thus forming a raised structure protruding towards the bowel, which is stiffened and held in place by the ring. This may also expose the polypropylene side of the mesh to the bowel and other internal organs.

79. Defendants knew at the time they distributed the PET-ringed Devices that the PET rings in their devices could break or buckle causing patients to suffer severe injuries, including: perforation of the bowel; ring migration through the abdominal wall; chronic enteric fistulae; infection; abscesses; bowel obstruction; chronic abdominal pain; peritonitis; sepsis; and adhesions between the bowel and the Device; and other injuries.

80. Evidence of contraction forces causing a ringed-hernia mesh device to buckle was first seen in 1997 from adverse events reported with the Kugel Patch (the ringed predecessor to the Composix Kugel and Ventralex ePTFE Devices).

81. Indeed, buckling was seen in the Kugel and Ventralex Patches from the very beginning: Defendants' own internal analysis observed small ripples called "buckling" or "kinks" in the final products even before they were implanted.

82. Buckling and folds of the PET ring were also reported in early patient complications with the Composix Kugel Hernia Patch and Ventralex Patch.

83. For example, Defendants received a complaint on or about October 6, 2002, reporting that the outer edge of a Composix Kugel Hernia Patch buckled, formed a sharp edge,

and caused the ePTFE portion of the patch to protrude inwards 5 mm towards the bowel, causing a fistula.

84. On April 14, 2003, an e-mail chain between Defendants' employees discussed a complaint received by Bard Angiomed, in which "the edge of the mesh had folded around underneath the memory recoil ring resulting in adhesion of the tissue to the polypropylene layer of the memory recoil ring."

85. In January 2002, Defendants submitted a physician survey that asked doctors: "Are there any concerns of the prosthesis buckling, allowing for bowel to come intact [sic] with mesh, when the patient bends over?" This was done because Defendants knew buckling of the PET-ringed Devices was a risk before the PET-ringed Devices were released to market.

86. However, Defendants' employees admitted that they failed to adequately investigate or test these risks. As Davol employee David Paolo admitted:

> The design inputs were not properly investigated to make sure that the design team understood all the potential ramifications and specifications that were set. In other words, there wasn't enough input taken in before the product was actually designed and developed. The specs were set without the proper input.
>
> * * *
>
> The design validation, which, again, is performed in the clinical state or clinical setting, did not - was not robust enough to make sure that the design team had all the necessary input that the design that they were trying to produce was being validated to the right level of confidence.

87. Stephen Clarke, a product development engineer for Defendants' Hernia Mesh Devices, admitted he was aware by 2003 that buckling patches were coming into contact with the bowel. Mr. Clarke further admitted that this was communicated "through the team at team meetings." The "team would be alerted to it and would consider it in their design/development."

88. Likewise, Davol employee Jim Keegan admitted he was aware in November of 2004 of the concern that contracture of a polypropylene mesh against the rigid PET ring may cause the ring to deform.

89. In a patent application dated January 7, 2002, Defendants described the problem in the following way: "after the prosthesis is inserted in position, or during implantation, a portion of the prosthesis may become folded or otherwise move and become susceptible to undesirable tissue, muscle or organ adhesions." (U.S. Patent Number 6,790, 213 B2 p.12).

90. Davol employee Tom Swanson acknowledged these buckling problems in an email dated June 15, 2006. Dennis Cherok responded on the same day: "buckling could be a result of tissue ingrowth and the resultant contracture of the mesh in the patch; the ring can't contract."

91. In 2009, Defendants finally conducted studies on the performance of ring structures in pigs. (DaVinci Studies DB-283, Dh-283, and DB-288). These studies confirmed what Defendants had already long known: buckling is caused by scar contracture and can lead to folded or raised rigid structures protruding into the bowel.

92. On or about January 2006, the FDA inspected Defendants' facility in Cranston, Rhode Island, where they manufactured Composix Kugel Hernia Patches and Ventralex Patches. This inspection resulted in the FDA issuing an Establishment Inspection Report ("EIR") in 2006. The 2006 EIR found that the post-market survey validation process of the Composix Kugel Hernia Patch was incomplete and failed to include all data from physicians surveyed during this time, including data demonstrating unfavorable or "dissatisfied" results. Defendants actively concealed these complaints and concerns of physician surveyors from Plaintiffs, their health care providers, and others.

93. By at least 2003, Defendants were aware of serious problems with the weld process involving the PET memory recoil ring. Despite attempts to correct the problem at the manufacturing plant, Defendants found the corrective measures to be ineffective and the process still not in control. Defendants knew that these weld issues had existed from the time the Composix Kugel Hernia Patch and Ventralex Patches were first released to market and that all sizes and lots suffered from this dangerous defect. But they intentionally withheld the information at this time from the FDA, Plaintiffs, health care providers, and others.

94. According to the 2006 EIR, Defendants' corporate executives informed the FDA that the spring and summer period of 2005 showed a marked increase in the number of adverse event complaints regarding the Composix Kugel Hernia Patch and the PET ring.

95. Notwithstanding Defendants' knowledge of increasing complaints and complications associated with the PET-ringed Devices, they did not cease distribution or make any effort to notify the FDA, Plaintiffs, health care providers and others, of the true risks associated with these unreasonably dangerous and defective devices until late December 2005.

96. Even then, Defendants limited the December 2005 recall to "Extra Large" sized Composix Kugel Hernia Patch products, despite knowing of substantial numbers of similar serious adverse events associated with other nonrecalled PET-ringed Devices; and knowing that all such Devices were developed, tested, designed, manufactured, inspected, marketed, labeled, promoted and intended for use in a similar fashion, and therefore subject to the same health risks and defects as the recalled devices. Defendants further violated federal law by not timely notifying the FDA of the December 2005 recall.

97. The FDA determined the December 2005 recall to be a Class 1 recall. Class 1 recalls are the most serious type of recalls and involve situations in which the FDA believes there is a reasonable probability that use of the product will cause serious injury or death.

98. The basis for the recall was that the PET ring in the Composix Kugel Hernia Patch can break under stress or pressure, including the stress of implantation. But Defendants failed to disclose, and continued to deny to the public, that the PET ring can buckle or break and injure the viscera, even when the device is properly placed.

99. As mentioned above, the FDA conducted investigations of a Cranston, Rhode Island facility owned, managed, and operated by Defendants. The subsequently issued 2006 EIR determined, among other things, that Defendants had:

a. excluded memory recoil ring failure events from their complication database, reports, and recall notices, although they should have been included;
b. misidentified numerous Composix Kugel Hernia Patch complication events;
c. failed to apply product quality hold and release procedures on a timely basis;
d. failed to follow proper procedures for conducting design validation review;
e. failed to identify all actions necessary to correct and prevent recurrence of further ring break and Composix Kugel Hernia Patch complications; specifically, by not providing justification for including only Extra Large Composix Kugel Patch sizes in the December 2005 recall;
f. failed to provide all reasonably known information regarding numerous Composix Kugel Hernia Patch complaints; and specifically noting that company officials had "understated" in several reports to the FDA the potential severity of device-related injuries, including a possible device-related death;
g. failed to perform strength testing on PET rings before placing them on the market; and

h. failed to maintain appropriate sources for quality data to identify, track, and trend existing and potential causes for PET ring failures and hernia patch complaints, resulting in numerous inconsistencies and errors in the raw data, actual complaints, and electronic databases.

100. On March 24, 2006, Defendants expanded the Class 1 recall to include the following Composix Kugel Hernia Patch sizes: 1) "Oval" Patches; 2) "Large Circle" Patches; and 3) "Large Oval" Patches.

101. In January 2007, Defendants expanded the recall for a second time, to include further production lots of the Large Oval and Large Circle Composix Kugel Hernia Patch Devices. However, Defendants still refused to recall several varieties of the Composix Kugel Hernia Patch or any sizes of the Ventralex Patch.

102. On January 23, 2007 through March 13, 2007, the FDA again inspected Defendants' Cranston, Rhode Island facility. On April 24, 2007, the FDA issued a "Warning Letter" to Defendants, notifying them that the inspection had again uncovered "serious violations of the law" regarding the quality assurance program used in the manufacture of Defendants' PET-ringed Hernia Mesh Devices. These violations were of such a degree and nature that the FDA determined the Composix Kugel Hernia Patch to be "adulterated" under Section 501(h) of the Federal Food, Drug and Cosmetic Act. The Warning Letter specifically mentions, among other things, the following violations by Defendants:

a. failing to establish and maintain adequate corrective and preventative action procedures that ensure identification of actions needed to correct and prevent the recurrence of nonconforming product and other quality problems;
b. failing to document the implementation of corrective and preventative actions;

c. failing to validate the Device's design to ensure that it conformed to defined user needs and intended uses;

d. failing to establish procedures to completely address the identification, documentation, evaluation, segregation, disposition and investigation of a non-conforming product; and

e. failing to establish adequate management controls to ensure that an effective quality system has been established and maintained.

The Warning Letter notes that as an example of the last enumerated violation, Defendants' "quality system failures" resulted in the delayed recall of Defendants' Hernia Mesh Devices.

103. During the same time frame, BioAssist, Defendants' own outside auditor, criticized them for not adequately tracking and trending complaints, including complaints for bent PET memory rings. BioAssist also found that the Design Failure Mode and Effect Analysis (DFMEA) for these devices did not address bending or kinking of the PET ring, even though that failure was "prevalent in product complaints." Moreover, BioAssist determined that the "complaint files are so poorly organized and presented that the ability to locate and understand important technical data, decisions, and objective evidence is significantly compromised."

104. Even when Defendants did become aware of the unreasonably dangerous nature of the Composix Kugel Hernia Patch and Ventralex Patch, they failed to take timely and adequate corrective action. In early October 2003, Defendants attempted to address problems with the PET ring by increasing the strength of the PET ring in the Composix Kugel Hernia Patch. However, Defendants did not recall any of their formerly manufactured and sold patches, despite the information they had about problems with the PET rings. Defendants were also aware that the PET rings in both the Composix Kugel Hernia Patch and Ventralex Patches continued to break

and buckle resulting in serious patient injuries. Thus, Defendants were on notice that to achieve patient safety, the design of the PET-ringed Devices had to be altered to remove the PET ring.

105. Despite Defendants' knowledge of the dangers posed by their PET rings, Defendants never issued a recall for the Ventralex Patch, Kugel, Modified Kugel, or for many models of the Composix Kugel Hernia Patch.

DISCOVERY RULE; STATUTORY OR EQUITABLE TOLLING; ESTOPPEL

106. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including statutory and equitable tolling, delayed discovery, discovery rule, and/or fraudulent concealment.

107. The discovery rule applies to toll limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating their injuries; the cause of the injuries; or the tortious nature of the wrongdoing that caused the injuries.

108. The nature of Plaintiffs' injuries, damages, or their resulting relationship to Defendants' conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims.

109. Limitations are tolled due to equitable or statutory tolling. Defendants are therefore estopped from asserting a statute of limitations defense due to their fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and their health care providers of the risks and defects associated with Defendants' Hernia Mesh Devices, including the severity, duration and frequency of risks and complications. Defendants affirmatively withheld and/or intentionally misrepresented facts concerning the safety of their Devices, including adverse

data and information from studies and testing conducted with respect to the Devices, showing that the risks and dangers associated with the Hernia Mesh Devices were unreasonable.

110. As a result of Defendants' misrepresentations and concealment, Plaintiffs and their health care providers were unaware, and could not have known or have learned through reasonable diligence, that Plaintiffs had been exposed to the risks alleged in this Master Complaint; and that those risks were the direct and proximate result of Defendants' wrongful acts and or omissions. Defendants are estopped from asserting any limitations defense based on their intentional acts of withholding material information about the safety of the Hernia Mesh Devices from Plaintiffs and their health care providers.

IV. COUNTS

COUNT I
STRICT PRODUCT LIABILITY: DEFECTIVE DESIGN

111. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

112. Defendants' Hernia Mesh Devices are defectively designed and unreasonably dangerous.

113. At the time their Hernia Mesh Devices were implanted in Plaintiffs, the Devices were defectively designed. As described in this Master Complaint, there was an unreasonable risk that a Device would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning the risks.

114. Defendants' Hernia Mesh Devices were defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when they were implanted in Plaintiffs.

115. Defendants expected and intended the Hernia Mesh Devices to reach users like Plaintiffs in the condition in which the Devices were sold.

116. The implantation of Hernia Mesh Devices into Plaintiffs was medically reasonable, and was the type of use Defendants intended and foresaw when they designed, manufactured and sold the Devices.

117. The risks of all Hernia Mesh Devices' designs significantly outweigh any benefits allegedly associated with the designs.

118. The appropriate treatment for complications associated with any Hernia Mesh Device involves additional invasive surgery to remove the implanted mesh and to repair the damage caused by the failed Device, thus eliminating any purported benefit that the product was intended to provide.

119. When the Hernia Mesh Devices were implanted in Plaintiffs, there existed safer alternative designs for hernia mesh products, which were economically and technologically feasible at the time the Devices left Defendants' control. In all reasonable probability, those alternative designs would have reduced the likelihood, severity, frequency, and duration of the injuries Plaintiffs suffered, without substantially impairing the utility of the hernia mesh products.

120. The Hernia Mesh Devices implanted in Plaintiffs failed to reasonably perform as intended and resulted in complications. In many cases, these complications necessitated further surgery to repair the injuries caused by the defective Devices, and to repair the very issue the Devices were intended to repair. Thus, the Devices provided no benefit to Plaintiffs.

121. Defendants' Hernia Mesh Devices failed consumer safety expectations, as they did not perform as safely, when used in an intended or reasonably foreseeable manner, as an ordinary consumer would have expected.

122. Defendants' Hernia Mesh Devices injured Plaintiffs.

123. Defendants are strictly liable to Plaintiffs for designing defective products. Defendants' actions give rise to a claim for damages under the product liability statutes and common law jurisprudence in all states and territories of the U.S.

124. As a direct and proximate result of Defendants' defectively designed Hernia Mesh Devices, Plaintiffs have been injured and undergone medical treatment, and/or will likely undergo future medical treatment. They also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

125. Plaintiffs are entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries sustained as a result of Defendants' defectively designed Hernia Mesh Devices.

COUNT II
STRICT PRODUCT LIABILITY: FAILURE TO WARN

126. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

127. Defendants Davol and Bard were manufacturers, distributors, and/or retailers of Hernia Mesh Devices.

128. Their Devices are inherently dangerous.

129. The use of any of Defendants' Hernia Mesh Devices in a reasonably foreseeable manner involves a substantial danger that a user would not readily recognize.

130. Defendants knew or should have known of these dangers, given the generally recognized and prevailing scientific knowledge available at the time of the manufacture and distribution of their Hernia Mesh Devices.

131. Defendants failed to provide adequate warning of the dangers created by the reasonably foreseeable use of their Devices.

132. At the time the Devices were implanted in Plaintiffs, Defendants' warnings and instructions for them were inadequate and defective. As described in this Master Complaint, there was an unreasonable risk that any Device would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

133. Defendants failed to properly and adequately warn and instruct Plaintiffs and their health care providers concerning the risks of Hernia Mesh Devices, given Plaintiffs' conditions and need for that information.

134. Defendants also failed to properly and adequately warn and instruct Plaintiffs and their health care providers concerning the inadequate research and testing of Hernia Mesh Devices, and the complete lack of a safe, effective procedure for removal of the Devices.

135. Defendants expected and intended the Hernia Mesh Devices to reach Plaintiffs, their health care providers, and other consumers in the condition in which their products were sold.

136. Plaintiffs and their health care providers were unaware of the defects and dangers of Hernia Mesh Devices; and were further unaware of the frequency, severity, and duration of the defects and risks associated with the Devices.

137. Defendants' Instructions for Use for the Devices expressly understated, misstated, or concealed the risks Defendants knew or should have known were associated specifically with them, as described in this Master Complaint.

138. Defendants' Instructions for Use for the Hernia Mesh Devices failed to adequately warn Plaintiffs or their health care providers of numerous risks Defendants knew or should have known were associated with the Devices.

139. Defendants failed to adequately train or warn Plaintiffs or their health care providers about the necessity for surgical intervention in the event of complications, or how to properly treat such complications associated with the Hernia Mesh Devices when they occurred.

140. Defendants failed to adequately warn Plaintiffs, their health care providers, and the general public, that the necessary surgical removal of a Hernia Mesh Device in the event of complications would leave the hernia unrepaired, and would necessitate a further attempt to repair the same hernia that the failed Device was intended to treat.

141. With respect to Defendants' warnings about complications associated with the Devices, they provided inadequate or no information regarding the complications, frequency, severity, and duration, even though the complications were more frequent and more severe, and lasted longer than those associated with safer feasible alternative hernia repair treatments.

142. If Plaintiffs or their health care providers had been properly warned of the defects and dangers of Hernia Mesh Devices, and of the frequency, severity and duration of the risks associated with the Devices, Plaintiffs would not have consented to allow the Devices to be implanted, nor would their health care providers have implanted them.

143. Defendants are strictly liable in tort to Plaintiffs for their wrongful conduct, including their failure to warn or provide adequate instructions regarding Hernia Mesh Devices.

Defendants' actions give rise to a claim for damages under the product liability statutes and common law jurisprudence of all states.

144. As a direct and proximate result of Defendants' inadequate and defective warnings and instructions, Plaintiffs have been injured and undergone medical treatment, and will likely undergo future medical treatment. They have also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, and other damages (and in some cases death).

145. Plaintiffs' injuries were a reasonably foreseeable result of Defendants' failure to provide adequate warnings and instructions.

146. Plaintiffs are entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries sustained as a result of Defendants' failure to provide adequate warnings and instructions on the risks and dangers associated with their Hernia Mesh Devices.

147. As a result of Defendants' failure to warn or to provide adequate warnings, Plaintiffs and their health care providers were unaware, and could not have known or learned through reasonable diligence, that Plaintiffs had been exposed to the risks alleged in this Master Complaint; and that those risks were the direct and proximate result of Defendants' wrongful acts and/or omissions.

COUNT III
STRICT PRODUCT LIABILITY: MANUFACTURING DEFECT

148. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

149. Defendants' Hernia Mesh Devices were not reasonably safe for their intended use and were defective with respect to their manufacture, in that they deviated materially from Defendants' manufacturing and/or design specifications, and thus posed unreasonable risks of serious bodily harm to Plaintiffs.

150. Defendants' Hernia Mesh Devices were unreasonably dangerous as a result of a malfunction, failure to properly manufacture to specifications as intended, improper assembly, or improperly broken or damaged packaging.

151. At the time the Hernia Mesh Devices were implanted, the Devices were defective with respect to their manufacture, in that Defendants deviated materially from their manufacturing and/or design specifications and thus posed an unreasonable risk of harm to Plaintiffs in whom the Hernia Mesh Devices were implanted.

152. The manufacturing defects associated with the Hernia Mesh Devices were not known, knowable or readily visible to Plaintiffs' health care providers or to Plaintiffs, nor were they discoverable upon reasonable examination. The Hernia Mesh Devices were used and implanted in the very manner in which they were intended to be used and implanted, in accordance with Defendants' Instructions for Use and marketing materials.

153. The Hernia Mesh Devices implanted in Plaintiffs were different from their intended design, and failed to perform as safely as Devices manufactured in accordance with the intended design would have performed.

154. As a direct and proximate result of the aforementioned defects, Plaintiffs have been injured and undergone medical treatment and will likely undergo future medical treatment and procedures. They have also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic

loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

155. Defendants' defective manufacture of Hernia Mesh Devices was a proximate cause of the damages and injuries Plaintiffs suffered.

156. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging and selling defective Hernia Mesh Devices.

157. Defendants' actions give rise to a claim for damages under the product liability statutes and common law jurisprudence of all states.

158. Plaintiffs are entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries sustained as a result of Defendants' defectively manufactured Hernia Mesh Devices.

COUNT IV
NEGLIGENCE

159. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

160. Defendants owed a duty to Plaintiffs to exercise reasonable care when designing, manufacturing, producing, marketing, labeling, packaging and selling Defendants' Hernia Mesh Devices, and when creating instructions and warnings for them.

161. Defendants did not exercise reasonable care when designing, manufacturing, producing, labeling, packaging, marketing, selling, creating, and explaining the instructions or warnings for the Devices.

162. In addition to the acts and omissions described in this Master Complaint, Defendants, by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence and/or willful,

wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, creating instructions and warnings, marketing, distributing, supplying, selling and/or placing into the stream of commerce their Hernia Mesh Devices, including but not limited to the following:

a) failing to use due care in design and/or manufacture of the Hernia Mesh Devices so as to avoid the aforementioned risks to Plaintiffs and others;

b) failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their Hernia Mesh Devices;

c) failing to recognize the significance of their own and other testing, and information regarding their Hernia Mesh Devices, which testing and information evidenced such products are dangerous and potentially harmful when implanted in humans;

d) failing to respond promptly and appropriately to their own and other testing, and information regarding the Hernia Mesh Devices; and failing to promptly and adequately warn of the injuries as described in this Master Complaint;

e) failing to promptly, adequately and appropriately recommend monitoring of patients implanted with the Hernia Mesh Devices, in light of the Devices' dangers and potential harm to humans;

f) failing to properly, appropriately and adequately monitor the post-market performance of their Hernia Mesh Devices;

g) aggressively promoting, marketing, advertising and/or selling their Hernia Mesh Devices despite their knowledge and experience of the Devices' dangers and risks;

h) failing to use reasonable and prudent care in their statements of the efficacy, safety and risks of implanting the Hernia Mesh Devices, which were knowingly false and misleading, in order to influence patients' health care providers to implant the Devices;

i) failing to accompany their Hernia Mesh Devices with proper and adequate warnings regarding all possible adverse effects and risks associated with the implantation of the Devices;

j) failing to disclose to Plaintiffs and their health care providers their full knowledge and experience regarding the potential risks and harm associated with the implantation of the Hernia Mesh Devices;

k) failing to disclose to Plaintiffs and their health care providers in an appropriate and timely manner, facts relative to the potential risks and harm associated with the implantation of the Hernia Mesh Devices;

l) failing to warn Plaintiffs and their health care providers of the severity and duration of such adverse effects;

m) failing to warn Plaintiffs and their health care providers directly or indirectly, whether orally or in writing, before actively encouraging the sale of their Hernia Mesh Devices, about the increased risk associated with the Devices;

n) placing and/or permitting the placement of the Hernia Mesh Devices into the stream of commerce without adequate warnings that their implantation is harmful to humans and/or without proper warnings of the Devices' risks;

o) failing to respond or react promptly and appropriately to reports that the Hernia Mesh Devices caused harm to patients;

p) disregarding government and/or industry studies, information, documentation and recommendations, consumer complaints and reports or other information regarding the hazards of implantation of the Hernia Mesh Devices and their potential harm to humans;

q) under-reporting, underestimating or downplaying the serious dangers and risks of their Hernia Mesh Devices;

r) failing to exercise reasonable care in informing health care providers implanting the Hernia Mesh Devices about Defendants' own knowledge regarding the potential risks and harm associated with the implantation of the Devices;

s) failing to adequately warn Plaintiffs and their health care providers of the known or reasonably foreseeable danger that Plaintiffs would suffer serious injuries or death after being implanted with their Hernia Mesh Devices;

t) promoting the Hernia Mesh Devices in advertisements, websites and other modes of communication aimed at creating or increasing the rate and frequency of implantation of the Devices, without regard to the dangers and risks associated with their implantation;

u) failing to conduct or respond to post-marketing surveillance of complications and injuries associated with the implantation of the Hernia Mesh Devices;

v) failing to use due care under the circumstances; and

w) other acts or omissions constituting negligence and carelessness, as may appear during the course of discovery or at the trial of this matter.

163. Defendants knew or should have known that their failure to exercise ordinary care in the manufacture, design, packaging, labeling, the creation of warnings and instructions, sale, marketing and distribution of the Devices, and their training of health care providers to implant the Devices or to treat Device complications, would cause foreseeable harm, injuries, and damages to individuals implanted with Hernia Mesh Devices, including Plaintiffs.

164. Defendants knew, or in the exercise of reasonable care should have known, that the Hernia Mesh Devices were defectively and unreasonably manufactured and/or designed, and were unreasonably dangerous and likely to injure patients in whom Hernia Mesh Devices were implanted. Defendants knew or should have known that Plaintiffs and their health care providers were unaware of the dangers and defects inherent in the Devices.

165. Defendants' Hernia Mesh Devices caused Plaintiffs to suffer injuries.

166. Plaintiffs suffered injuries as a result of Defendants' failure to exercise reasonable care in designing, manufacturing, producing, marketing, labeling, packaging and selling, and creating instructions or warnings for Hernia Mesh Devices.

167. Defendants' actions constitute negligence under the common law of all states.

168. Defendants' negligence proximately caused the damages and injuries to Plaintiffs.

169. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing and training, and preparing inadequate and improper written instructions and warnings for Hernia Mesh Devices, Plaintiffs have been injured and undergone medical treatment, and will likely undergo future medical treatment and procedures, sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic

loss, and damages, including, but not limited to, medical expenses, lost income, other damages (and in some cases death).

170. Plaintiffs are entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries resulting from Defendants' negligence.

COUNT V
NEGLIGENCE PER SE

171. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

172. Defendants' actions also constitute negligence per se under the applicable health and safety statutes and regulations of all state, as well as federal law.

173. The applicable statutes and regulations are aimed at preserving the health and safety of Plaintiffs and the general public.

174. Plaintiffs are among the class of individuals that the statutes and regulations were meant to protect.

175. Plaintiffs' injuries are among the type that the statutes and regulations were intended to prevent.

176. As a result of the acts and omissions described in this Master Complaint, Plaintiffs were caused to suffer serious injuries as described in this Master Complaint, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

177. Defendants' negligence per se proximately caused the damages and injuries to Plaintiffs.

178. Plaintiffs are entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries resulting from Defendants' negligence per se.

COUNT VI
GROSS NEGLIGENCE

179. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

180. Defendants' conduct, as described in this Master Complaint, was extreme and outrageous. Defendants risked the lives of Plaintiffs, and other consumers and users of their products, with knowledge of the safety and efficacy problems with their drugs; and they withheld their knowledge from Plaintiffs, their health care providers, and others. Further, Defendants made conscious decisions not to redesign, re-label, warn or inform unsuspecting consumers.

181. Defendants' wrongs were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs, for which the law would allow—and for which Plaintiffs will seek at the appropriate time under governing law—the imposition of exemplary damages. Defendants' conduct was specifically intended to cause substantial injury to Plaintiffs, or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Further, Defendants were actually subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others, including Plaintiffs. Defendants' outrageous conduct warrants an award of punitive damages.

182. As a direct and proximate result of Defendants' gross negligence, Plaintiffs have been injured and undergone medical treatment, and will likely undergo future medical treatment. They have also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

183. Defendants' actions constitute gross negligence under the common law of all states.

184. Plaintiffs allege that the acts and omissions of Defendants, whether taken alone or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary damages in an amount to punish Defendants for their conduct, and to deter other manufacturers from engaging in such misconduct in the future.

COUNT VII
STATE CONSUMER PROTECTION LAWS

185. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

186. Plaintiffs purchased and used Defendants' Hernia Mesh Devices primarily for personal use. Therefore, each Plaintiff suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws applicable in the state where the Device was purchased and used.

187. Had Defendants properly advised Plaintiffs or their health care providers of the defects and risks associated with the Hernia Mesh Devices, including the frequency, severity and duration of those risks, Plaintiffs would not have purchased or paid for the Devices, would not have consented to allow the Devices to be implanted, and would not have suffered injuries and incurred related medical costs.

188. Defendants engaged in wrongful conduct, while at the same time obtaining under false pretenses moneys from Plaintiffs for Hernia Mesh Devices, which Plaintiffs would not have paid had Defendants not engaged in unfair and deceptive conduct.

189. Deceptive acts or practices proscribed by law include the following:

a. representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

b. advertising goods or services with the intent not to sell them as advertised; and

c. engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

190. The cumulative effect of Defendants' conduct directed at Plaintiffs, their health care providers, and the general public, was to create demand for and sell Hernia Mesh Devices. Each aspect of Defendants' conduct combined to artificially create sales of their Devices.

191. Plaintiffs were injured by the cumulative nature of Defendants' conduct.

192. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of their Hernia Mesh Devices throughout the states.

193. Defendants' deceptive, unconscionable or fraudulent representations, or material omissions to Plaintiffs, their health care providers, and the general public, constituted unfair and deceptive acts and trade practices in violation of the consumer protection statutes of all states.

194. Defendants' actions constitute unfair, unconscionable, deceptive or fraudulent acts or trade practices, in violation of consumer protection statutes and regulations in states where the purchases and/or implantation of the Hernia Mesh Devices occurred.

195. Under applicable state laws protecting consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, making them subject to liability under such state law for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

196. Defendants violated the laws in states where the purchase and/or implantation of Hernia Mesh Devices occurred. Those state laws were enacted to protect consumers against unfair,

deceptive, fraudulent and unconscionable trade and business practices and false advertising. Defendants' violations occurred by their knowingly false representations that the Hernia Mesh Devices were fit for the purpose for which the Devices were intended, when in fact they were defective and dangerous; and by other acts alleged in this Master Complaint.

197. Defendants' acts and omissions are uncured or incurable deceptive acts under all state laws enacted to protect consumers, including Plaintiffs, against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising. Defendants had actual knowledge of the defective and dangerous conditions of their Hernia Mesh Devices but failed to take any action to cure such defective and dangerous conditions.

198. Plaintiffs, their health care providers, and the general public, relied upon Defendants' misrepresentations and omissions in determining to use the Hernia Mesh Devices or in allowing the Devices to be implanted.

199. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiffs have been injured and undergone medical treatment, and will likely undergo future medical treatment. They have also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

200. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiffs have sustained economic losses, injuries and other damages, and are entitled to statutory and compensatory damages in an amount to be proven at trial.

COUNT VIII
BREACH OF IMPLIED WARRANTY

201. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

202. Defendants sold the Hernia Mesh Devices implanted in Plaintiffs.

203. Defendants knew or reasonably should have known at the time of sale, that each Hernia Mesh Device was intended to be used for the purpose of hernia repair through surgical implantation in the human body.

204. Defendants warranted to Plaintiffs, their health care providers, and other consumers, that the Devices were of merchantable quality, and safe for the use for which they were intended.

205. Plaintiffs and their health care providers reasonably relied on Defendants' judgment, indications, and statements that Hernia Mesh Devices were fit for such use. Because of that reliance, Defendants' Hernia Mesh Devices were implanted in Plaintiffs.

206. Defendants distributed into the stream of commerce and sold Hernia Mesh Devices that were unsafe for their intended use, and not of merchantable quality as warranted by Defendants, in that the Devices had dangerous propensities when used as intended and implanted.

207. As a result of Defendants' conduct, Plaintiffs suffered injuries and damages, making Defendants liable for breaching their implied warranties.

208. As a direct and proximate result of Defendants' breach of the implied warranties associated with their Hernia Mesh Devices, Plaintiffs have been injured and undergone medical treatment, and will likely undergo future medical treatment. They have also sustained severe and permanent physical and mental pain and suffering, disability, impairment, loss of enjoyment of

life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

COUNT IX
BREACH OF EXPRESS WARRANTY

209. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

210. Defendants warranted and represented to Plaintiffs, their health care providers, and other consumers, that their Hernia Mesh Devices were safe and reasonably fit for their intended purposes.

211. Plaintiffs and their health care providers chose Hernia Mesh Devices based upon Defendants' warranties and representations regarding the safety and fitness of their Devices, as described in this Master Complaint.

212. Plaintiffs and their health care providers reasonably relied upon Defendants' express warranties and guarantees that the Devices were safe, merchantable, and reasonably fit for their intended purposes.

213. Defendants breached these express warranties because their Hernia Mesh Devices were unreasonably dangerous and defective, and not as Defendants had represented them to be.

214. Defendants' breach of their express warranties resulted in the implantations of unreasonably dangerous and defective Hernia Mesh Devices in Plaintiffs, placing their health and safety in jeopardy.

215. As a direct and proximate result of Defendants' breach of the express warranties associated with Hernia Mesh Devices, Plaintiffs have been injured and undergone medical treatment, and will likely undergo future medical treatment. They have also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life,

loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

COUNT X
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

216. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

217. As described in this Master Complaint, Defendants engaged in negligent conduct by failing to use due care in adequately designing and constructing effective and safe Hernia Mesh Devices, by failing to warn of their dangerous propensities, and by negligently studying, designing, developing, testing, inspecting, manufacturing, advertising, marketing, promoting, labeling, distributing, and/or selling the Hernia Mesh Devices.

218. As a direct and proximate result of Defendants' negligence, Plaintiffs have suffered severe emotional distress, as well as economic loss, and damages, including medical expenses, lost income, and other damages.

219. The emotional distress damages Plaintiffs incurred were a reasonably foreseeable result of Defendants' actions.

220. Defendants' actions constitute negligent infliction of emotional distress under the common law of all states.

COUNT XI
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

221. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

222. As described in this Master Complaint, Defendants engaged in intentional, willful, reckless, extreme, and outrageous conduct by failing to adequately design and construct effective

and safe Hernia Mesh Devices, by failing to warn of their dangerous propensities, and by improperly studying, designing, developing, testing, inspecting, manufacturing, advertising, marketing, promoting, labeling, distributing, and/or selling the Devices.

223. The emotional distress damages Plaintiffs incurred were a reasonably foreseeable result of Defendants' actions.

224. Defendants' actions constitute intentional infliction of emotional distress under the common law of all states.

COUNT XII
NEGLIGENT MISREPRESENTATION

225. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

226. From the time Defendants' Hernia Mesh Devices were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, through the present, Defendants made misrepresentations to Plaintiffs, their health care providers, and the general public. Defendants' misrepresentations included but were not limited to representing that the Hernia Mesh Devices were safe and effective for the repair of hernias. At all relevant times, Defendants conducted sales and marketing campaigns to promote the sale and implantation of the Hernia Mesh Devices and willfully deceived Plaintiffs, their health care providers, and the general public as to the health risks and consequences of the implantation of the Hernia Mesh Devices.

227. Defendants had a duty to ensure that the representations they made about their Devices were true and complete when made. Defendants made the foregoing representations without any reasonable ground for believing them to be true and complete.

228. At all relevant times, Defendants conducted sales and marketing campaigns to promote the sale and implantation of their Hernia Mesh Devices and deceived Plaintiffs and their

health care providers, as well as other consumers, as to the health risks and consequences of the use of their Hernia Mesh Devices.

229. Defendants made these false and misleading representations concerning the safety and efficacy of Hernia Mesh Devices for the repair of hernias without any reasonable ground for believing them to be true.

230. These false and misleading representations were made directly by Defendants, their sales representatives and other authorized agents, to Plaintiffs, their health care providers and the general public, in publications, the popular press, and other written materials directed to them; and on Internet websites and applications also directed to them, with the intention of inducing and influencing the demand for, and the ultimate implantation of, their Hernia Mesh Devices in Plaintiffs and other patients.

231. The above representations were in fact false, in that Defendants' Hernia Mesh Devices were not safe, fit or effective for permanent implantation as labeled; implanting the Devices was hazardous to consumers' health; and the Devices had a propensity to cause serious injuries to patients, as described in this Master Complaint.

232. Defendants' representations were made with the intention of inducing reliance and the ultimate implantation of the Devices in Plaintiffs and other patients.

233. In reliance on Defendants' false and misleading representations, Plaintiffs' health care providers were induced to purchase and recommend implantation of the Devices in Plaintiffs; and Plaintiffs were induced to consent to such implantation. If Plaintiffs or their health care providers had known the truth and the facts Defendants concealed, the health care providers would not have recommended, and Plaintiffs would not have consented to, the implantation of Defendants' Hernia Mesh Devices. The reliance of Plaintiffs and/or their health care providers on

Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities in a position to know all facts.

234. Defendants' acts and omissions caused Plaintiffs to suffer serious injuries that are permanent and lasting in nature (and in some cases death); physical pain and mental anguish; diminished enjoyment of life; and financial expenses for hospitalization and medical care.

235. Defendants' conduct, as described in this Master Complaint, was extreme and outrageous. Defendants risked the lives of the recipients of these Devices, including Plaintiffs, with knowledge of the safety and efficacy problems with their Hernia Mesh Devices and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' health care providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT XIII
FRAUD AND FRAUDULENT MISREPRESENTATION

236. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

237. Defendants designed, manufactured, marketed, and sold their Hernia Mesh Devices, and provided inadequate warnings and information about the Devices.

238. When Plaintiffs or their healthcare providers received the inadequate information and warnings, the Devices were defective and unreasonably dangerous for their intended and reasonably foreseeable use.

239. Further, Defendants fraudulently represented to Plaintiffs, their health care providers, and the general public that their Hernia Mesh Devices were safe and effective permanent implants. Additionally, even though Defendants were fully aware of the dangerous and defective

nature of the Devices, which could and did cause injuries such as those Plaintiffs suffered, Defendants intentionally concealed the defects in the Devices from Plaintiffs.

240. Defendants fraudulently represented to Plaintiffs, their health care providers, and the general public, that their Hernia Mesh Devices had been adequately tested, were safe for the repair of hernias, and were accompanied by adequate warnings.

241. Defendants widely advertised, marketed and promoted their Hernia Mesh Devices as safe and effective for permanent implantation in the human body, and for the repair of hernias.

242. Defendants made these representations with the intent of deceiving Plaintiffs, their health care providers, and other potential consumers; and with the intent of inducing the implantation of their Hernia Mesh Devices, under circumstances that Defendants knew were dangerous and unsafe, and created a high risk of harm.

243. Defendants also made material representations that were false. Further, Defendants knew they were false when made, or willfully, wantonly, and recklessly disregarded whether the representations were true or false. Defendants intended that Plaintiffs, their health care providers, and other potential consumers would rely and act upon the false representations.

244. Plaintiffs and/or their health care providers relied upon Defendants' fraudulent misrepresentations in allowing the defective Hernia Mesh Devices to be implanted. Plaintiffs thus sustained severe and permanent personal injuries, and/or were at an increased risk of sustaining severe and permanent personal injuries in the future.

245. Defendants knew or should have known that their Hernia Mesh Devices had not been sufficiently tested, were defective in nature and/or lacked adequate warnings and information.

246. Defendants' actions constituted common law fraud and/or fraudulent misrepresentation in all states.

247. As a direct and proximate result of Defendants' fraud or fraudulent misrepresentation, Plaintiffs have been injured and undergone medical treatment and will likely undergo future medical treatment and procedures. They have also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, other damages (and in some cases death).

COUNT XIV
FRAUDULENT CONCEALMENT

248. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

249. Before Defendants' Hernia Mesh Devices were implanted in Plaintiffs, Defendants fraudulently concealed material information regarding the safety and efficacy of their Hernia Mesh Devices, including information regarding adverse events, pre-marketing and post-marketing injuries, and literature indicating unreasonable risks associated with the implantation of the Hernia Mesh Devices.

250. Although Defendants were aware of the dangerous and defective condition of the Hernia Mesh Devices, they intentionally concealed such information from Plaintiffs, their health care providers, and the general public. The significant dangers Defendants concealed included a warning that the material was not suited for permanent human implantation. Further, the dangers were not readily obvious to the ordinary user of the Devices, even after post-implant complications had arisen.

251. Defendants made these omissions with the intent of defrauding and deceiving Plaintiffs and their health care providers specifically, and other consumers generally; and with the further intent of specifically inducing health care providers to recommend implantation of the

Hernia Mesh Devices. All such acts and omissions evinced Defendants' callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiffs.

252. When Defendants made the foregoing partial disclosures and fraudulent omissions, and at the time Plaintiffs were implanted with the Hernia Mesh Devices, Plaintiffs and/or their health care providers were unaware of their falsity and reasonably believed the misrepresentations and omissions to be true.

253. Defendants fraudulently concealed the safety issues associated with the implantation of their Hernia Mesh Devices, to induce health care providers to recommend implanting the Devices in patients like Plaintiffs, and to induce Plaintiffs to consent to the implantation of the Devices.

254. Plaintiffs' health care providers reasonably relied on Defendants' omissions when they recommended implantation of the Hernia Mesh Devices in Plaintiffs, thereby causing Plaintiffs to sustain severe and permanent personal injuries. Defendants knew, or should have known, that their Hernia Mesh Devices had not been sufficiently tested and were defective in nature, and/or that their Hernia Mesh Devices lacked adequate warnings.

255. Defendants also knew or should have known that their Hernia Mesh Devices had a potential to, and would, cause severe injury to those implanted with their Devices, and that the Devices were inherently dangerous in a manner exceeding any purported warnings.

256. Defendants had a duty to provide Plaintiffs, their health care providers, and the general public, with full, complete, accurate and truthful information concerning their Hernia Mesh Devices.

257. By virtue of Defendants' omissions and partial disclosures about the Hernia Mesh Devices, in which Defendants touted their Devices as a safe and effective for implantation in

patients, Defendants had a duty to disclose all facts about the risks associated with the Devices, including the risks described in this Master Complaint.

258. Plaintiffs' health care providers reasonably relied on these material and fraudulent omissions when recommending implantation of the Devices in Plaintiffs, and Plaintiffs reasonably relied on the material and fraudulent omissions when consenting to have the Devices implanted.

259. Defendants did not provide Plaintiffs' health care providers with the information necessary to adequately warn Plaintiffs.

260. The Hernia Mesh Devices were improperly marketed to Plaintiffs and their health care providers because Defendants did not provide proper instructions on how to implant the Devices and did not adequately warn about the risks associated with implantation.

261. Plaintiffs could not know in the exercise of reasonable diligence that Defendants' statements concerning their Hernia Mesh Devices were knowingly and intentionally false and misleading, or that Defendants had not disclosed material facts and information to Plaintiffs or their health care providers that would have been material to the choice of treatment.

262. As a direct and proximate result of Defendants' malicious and intentional concealment of material information from Plaintiffs and/or their health care providers, Defendants caused or contributed to Plaintiffs' injuries (and in some cases death).

263. Had Plaintiffs' health care providers been aware of the hazards associated with the implantation of Defendants' Hernia Mesh Devices, they would have used safer alternative devices for the repair of Plaintiffs' hernias.

264. Defendants' conduct was reckless, willful, wanton, and outrageous, and manifested a reckless indifference for the safety and well-being of Plaintiffs and other consumers.

265. As a direct and proximate result of Defendants' intentional and willful fraudulent concealment of material facts and information from Plaintiffs and/or their health care providers, Defendants caused, and increased the risk of harm of the injuries and damages Plaintiffs suffered after having been implanted with Defendants' Hernia Mesh Devices.

266. Had Plaintiffs been aware of the hazards associated with the implantation of the Hernia Mesh Devices, they would not have consented to their implantation.

267. Defendants actively and fraudulently concealed information in their exclusive possession regarding the hazards associated with the implantation of their Hernia Mesh Devices, for the purpose of preventing Plaintiffs and their health care providers from discovering these hazards.

268. Defendants' conduct was outrageous and shocked the conscience, and knowingly and intentionally placed considerations of financial gain, revenues and profits, market share and marketing advantage over patient safety and well-being.

269. As a result of the foregoing material and fraudulent omissions, Plaintiffs were caused to suffer serious injuries as described in this Master Complaint, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

270. Defendants' conduct, as described in this Master Complaint, was extreme and outrageous. Defendants risked the lives of Plaintiffs and other consumers and users of their products. Although Defendants had knowledge of the safety and efficacy problems with their Devices, they concealed this knowledge from Plaintiffs, their health care providers, and the general public. Further, Defendants made conscious decisions not to redesign, re-label, or warn unsuspecting consumers. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT XV
WRONGFUL DEATH

271. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

272. This wrongful death claim is brought on behalf of the estate and for the benefit of the lawful beneficiaries of Plaintiffs-decedents.

273. As a proximate result of Defendants' conduct and the defective nature of their Hernia Mesh Devices as described in this Master Complaint, Plaintiffs-decedents suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

274. By reason of the death of Plaintiffs-decedents, their heirs, next-of-kin and/or survivors (collectively beneficiaries) have suffered a pecuniary or non-pecuniary loss, including but not limited to support, income, services and guidance of Plaintiffs-decedents. All were permanently damaged as a result.

275. The beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a result of the Plaintiff-decedents' death caused by Defendants' wrongful conduct. The beneficiaries bring these claims for damages and for all pecuniary losses they sustained, pursuant to applicable state law.

COUNT XVI
LOSS OF CONSORTIUM

276. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

277. At all material times, and as specified in their Short Form Complaints, certain Plaintiffs had spouses, or others with standing to assert claims, who also suffered injuries and losses as a result of Defendants' Hernia Mesh Devices. Those individuals will be referred to as "Consortium Plaintiffs" in the Short Form Complaints.

278. As a direct and proximate result of Defendants' conduct, the Consortium Plaintiffs specified in the Short Form Complaints have suffered and will continue to suffer the loss of their Plaintiffs' support, companionship, services, society, love, and affection.

279. The Consortium Plaintiffs have suffered emotional pain and mental anguish.

280. Plaintiffs allege that their relationships have been impaired, and their associations altered as to all Consortium Plaintiffs.

281. The Consortium Plaintiffs have sustained and will continue to sustain physical injuries, severe emotional distress, economic losses, and other harm for which they are entitled to damages.

COUNT XVII
PUNITIVE DAMAGES

282. Plaintiffs reallege and incorporate by reference all paragraphs in this Master Complaint.

283. Defendants sold Hernia Mesh Devices to health care providers throughout the United States, without conducting adequate testing to ensure that the Devices were reasonably safe for implantation.

284. Defendants knew their Devices posed unreasonable risks, including degradation, excessive and chronic inflammation, inadequate or complete failure to incorporate in tissue, adhesion formation, migration, infection, erosion, abscess, fistula formation, nerve damage, excessive scarification, contracture, shrinkage, breakage, and other harm-causing defects.

285. Defendants sold their Hernia Mesh Devices to health care providers throughout the United States, despite knowing of these unreasonable risks.

286. At all material times, Defendants attempted to misrepresent, and did misrepresent, facts concerning the safety of their Hernia Mesh Devices, including adverse data and information from studies and testing conducted with respect to the Devices, which showed that the risks and dangers associated with the Devices were unreasonable.

287. Defendants' misrepresentations, omissions, and partial disclosures, included knowingly withholding material information from the medical community and the public, including Plaintiffs, concerning the safety and efficacy of Defendants' Hernia Mesh Devices.

288. At all material times, Defendants knew and intentionally and/or recklessly disregarded the fact that their Hernia Mesh Devices caused severe and potentially permanent complications with greater frequency than safer and feasible alternative devices or treatments.

289. Notwithstanding that knowledge, Defendants continued to market their Hernia Mesh Devices to consumers without disclosing the true risk of side effects and complications, or the frequency, severity and duration of those risks.

290. Defendants knew of their Devices' defective and unreasonably dangerous nature. But they continued to manufacture, produce, assemble, market, distribute, and sell the Devices, and failed to include adequate warnings about them. Defendants' acts and omissions were taken with reckless disregard of the foreseeable harm caused by the Hernia Mesh Devices, so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs.

291. Defendants' conduct described in this Master Complaint shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care raising the presumption of conscious indifference to consequences. Therefore, an award of punitive damages is justified.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, Davol, Inc. and C.R. Bard, Inc., jointly and severally, on each of the above claims or causes of action, as follows:

a) Compensatory damages in excess of $75,000, including, but not limited to damages for pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life, loss of consortium, wrongful death, and other noneconomic damages in an amount to be determined at trial;

b) economic damages in the form of medical expenses, out-of-pocket expenses, lost earnings and other economic damages, in an amount to be determined at trial;

c) punitive or exemplary damages for Defendants' wanton, willful, fraudulent, and reckless acts, established by their demonstration of complete disregard and reckless indifference for the safety and welfare of Plaintiffs and the general public, in an amount sufficient to punish Defendants and deter future similar conduct;

d) prejudgment interest;

e) post-judgment interest;

f) an award of reasonable attorneys' fees;

g) costs of these proceedings; and

h) any further relief this Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury as to all issues triable by jury.

Respectfully submitted,

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